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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,697	07/27/2006	Pentti Korhonen	43289-223931	2415

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EXAMINER
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GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/552,697

Applicant(s)

KORHONEN, PENTTI

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/06, 10/7/05</u>   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 37 and 55 are rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph as being indefinite. It is indefinite as to what beat, between two R-peaks, is being measured.
2. Claims 50 and 63 are rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph as being indefinite. It is indefinite and unclear as to what the "data storage unit" is, e.g., is it a ECG recording system or is it a computer on which ECG values were acquired and stored.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 34, 38-43, 49, 50-52, and 56-65, are rejected under 35 U.S.C. 102(b) as being anticipated by Groenewegen et al. (WO 01/76461).

In regard to claims 34, 43, 52, 61, and 65, Groenewegen et al. disclose a system and method for developing a database of body surface ECG p-wave data maps. The data maps may be stored in a computer-readable medium for retrieval, analysis, and sharing, page 6 lines 18-19 and 23-25. ECG signals are received from the heart via an

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array of multiple electrodes located in predetermined torso sites, p 12 lines 21-23. P wave onset and offset are determined, and grouping maps based on pattern similarities carries out a qualitative data classification. Other methods of data classification based on, e.g. pattern recognition algorithms, neural networks, statistical routines, etc, can also be used, p 13 lines 3-15; the Examiner considers this to anticipate the step of calculating parameters values based on said wave as the p wave data is placed in the said grouping maps based on certain characteristics. The potential maps are computed at 2-ms intervals, p 12 line 25 through p 13 line 1. The maps in the database are used to compare p wave data acquired in an ECG from patient in order for a physician to make a better diagnosis of an abnormality and make better treatment decisions, p 13 lines 20-25. The ECG p wave data maps for classification are considered to be reference values of p-wave data.

In regard to claims 38, 39, 56, and 57, the P wave classification maps serve as templates for collecting other P waves, and comparing them the patterns in contained within the P-wave maps in order to make a determination of a cardiac abnormality, p 7 lines 23-25 and p 13 lines 20-25.

In regard to claims 41 and 59, the series of maps of the p wave cycle is computed within a predetermined period of time, i.e., 2 ms, p 12 line 25 through p 13 line 1. Furthermore, mean (i.e., average) maps are computed of the classified maps, p 13 lines 15-17.

In regard to claims 42 and 60, the said mean maps contain mean body surface P-wave data maps for comparison to a patient's surface ECG p wave to improve

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classification and localization of cardiac abnormalities, e.g. left atrial arrhythmias, p 13 lines 18-20.

In regard to claims 49 and 62, Groenewegen et al. teach that is well known in the art to use a 12 lead ECG in an attempt to correlates changes in P wave morphology, p 5 lines 16-17.

In regard to claims 50 and 63, it is assumed that this invention can be performed with any well-known and available 12 lead ECG systems.

In regard to claims 51 and 64, the signal sensed at a time instant by sensors placed on a patient's chest is plotted can be plotted as a contour map or color map, p 13 lines 1-3.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 35-37, 44-48, 53-55, 58, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groenewegen et al. (WO 01/76461) in view of Toole (US PG-Pub. 2002/0082510).

In regard to claims 35, 37, 53, 55, and 66, Groenewegen et al. substantially describe the invention as claimed except for the focusing the cardiac analysis on the PQ- segment. Toole describes a method for analysis of the electrocardiogram and

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teaches that any segment of the ECG can be analyzed including the P, PQ, QRS, or ST-T segments, p 5 claim 7. Therefore, in view of this teaching it would be obvious.

In regard to claims 36, 40, 54, and 58, Groenewegen et al. substantially describe the invention as claimed except for representing the ECG signal as a vectorcardiogram. Groenewegen et al. does teach that early investigations of the ECG morphology have included vectors, p 2 lines 6-7. Toole teaches that another known method of ECG analysis, called vectorcardiogram, involves utilizing 3 leads, X, Y, and Z, to represent coordinate planes of the patients chest and to identify where the lead voltage are located. Therefore it would be obvious to use vectorcardiogram techniques since Toole teaches that the vectorcardiogram is useful in diagnosing abnormalities of the heart, para [0004].

In regard to claims 44-48, Groenewegen et al. substantially describe the invention as claimed except for the parameters associated with the p wave. Groenewegen et al. do teach that the p wave data is classified into maps based on certain characteristics of the P waves and can be ascertained by pattern recognition algorithms, neural networks, statistical routines, etc, p 13 lines 3-15. Toole et al. performs electrocardiogram analysis by means of vectorcardiography. Though Toole does not expressly state the claimed parameters, Toole does make calculations to verify cardiac abnormalities that involve vector orientation that include calculations of angles, magnitudes, etc. The Examiner contends that one of ordinary skill in art, particularly vector algebra and calculus, at the time the invention was made would be

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able to determine any of the various parameters and make insights into their meaning associated with cardiac abnormalities.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sun et al. (US Patent no. 5,755,739) and DuFault et al. (US Patent no. 4,721,114) both describe methods for detecting p waves from an ECG signal and identifying p wave morphologies.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon  
Patent Examiner  
Art Unit 3766



Robert E. Pezzuto  
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BTG